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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,641	09/25/2003	David E. Altobelli	1062/D43	6821
2101 7:	590 06/29/2006		EXAM	INER
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET			LOPEZ, AMADE	US SEBASTIAN
BOSTON, MA 02110-1618			ART UNIT	PAPER NUMBER
,		•	3743	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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FR 1.121(d). O-152.		
Stage		

	Application No.	Applicant(s)				
	10/670,641	ALTOBELLI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Amadeus S. Lopez	3743				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
<ol> <li>Responsive to communication(s) filed on <u>25 September 2003</u>.</li> <li>This action is <b>FINAL</b>. 2b) This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>						
Disposition of Claims						
<ul> <li>4)  Claim(s) 1-27 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,5-8,11-14,16-18 and 22-27 is/are rejected.</li> <li>7)  Claim(s) 2-4, 9-10, 15, 19, and 21 is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
9)⊠ The specification is objected to by the Examin 10)⊠ The drawing(s) filed on <u>25 September 2003</u> is Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11)□ The oath or declaration is objected to by the E	/are: a) accepted or b) to a drawing(s) be held in abeya ction is required if the drawing	nce. See 37 CFR 1.85(a). i(s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No	Summary (PTO-413) (s)/Mail Date Informal Patent Application (PTO-152)				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date _4/3/06 , 2/2/04 , 2/7/05 , 4/						

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#### **DETAILED ACTION**

#### Information Disclosure Statement

1. Most references disclosed in the information disclosure statements filed on 4/03/06, 2/02/04, 2/07/05, 4/1/05, and 3/14/05 were considered by the examiner. The references that were crossed off were duplicates or the disclosed inventor, issue date, or document number did not all match up.

#### **Drawings**

- 2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "400" has been used to designate both a chamber and an acoustic volume sensor within the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
- 3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 101 and 807 (page 16). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the

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application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

- 4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 507c, 1100,1103, and 1302. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
- 5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second processor

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must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

## Specification

6. The disclosure is objected to because of the following informalities:
On page 9 in the last line of paragraph 35, the appropriate serial number of the disclosed copending US patent application must be filled in place of the underline.

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Appropriate correction is required.

#### Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1, 5, 6, 7, is provisionally rejected on the ground of nonstatutory double patenting over claims 1 and 2 of copending Application No. 10/670924. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a variable acoustic source coupled to a volume, the volume being divided into an air region and a fluid region, the

fluid region having a fluid output; a microphone acoustically coupled to the volume; a processor configured to receive a signal from the microphone, and further configured to receive a signal from the microphone, and further configured to allow an amount of fluid to exit the fluid region, the amount of fluid being associated with the determined volume of the air region; and an atomizer coupled to the fluid output, the atomizer configured to aerosolize at least a portion of the amount of fluid to exit the fluid region (Claim 1).

Apparatus wherein the processor is configured to send a control signal to the fluid valve (Claim 2). Apparatus further comprising: a target region coupled to the fluid valve and in selective communication with an air tank through an air valve (Claim 2). An apparatus wherein the processor is further configured to send a control signal to the air valve (Claim 2).

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

#### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner assumes that the word "from" needs to be added after the phrase "receive a volume signal..."

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

- 9. Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5641892 to Larkins et al.
- 10. With regards to claim 11, what is taught and shown by Larkins et al. is a method comprising: receiving an acoustic signal representing an acoustic property of a volume (Col. 6, lines 60-63); calculating, using the received acoustic signal, a quantity associated with a first volume (Col. 6, line 67 to Col. 7, line 8); receiving a volume signal (Col. 7, lines 9-11); and outputting a signal for controlling a valve (Col. 7, lines 10-11),

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the output signal being associated with the received acoustic signal and with the received volume signal.

- 11. With regards to claim 12, what is taught and shown by Larkins et al. is a medium storing instructions to cause a processor to: receive an acoustic signal representing an acoustic property of a volume a quantity associated with a first fluid volume (Col. 6, lines 60-63 and Col. 6, line 67 to Col. 7, line 2); receive a volume signal a first processor (Col. 7, lines 9-11); and output a signal for controlling a valve (Col. 7, lines 10-11), the output signal being associated with the received acoustic signal and with the received volume signal.
- 12. Claims 13, 14, 18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6467476 to Ivri et al.
- 13. With regards to claim 13, what is taught and shown by lvri et al is an apparatus comprising: means for dispensing a first fluid (24; Col. 5, lines 23-31; Col. 6, lines 47-49); means for aerosolizing the first fluid in communication with the means for dispensing the first fluid (vibrator, thin shell member 38, and carrier plate 26; Fig. 1; Col. 5, lines 12-13); and means for determining aerosol volume coupled to the means for aerosolizing the first fluid (Controller 66; Col. 5, lines 16-31).
- 14. With regards to claim 14, what is taught and shown by Ivri et al is the apparatus wherein the means for dispensing the first fluid includes an acoustic volume transducer (microphone 178; Col. 5, lines 16-31).
- 15. With regards to claim 18 and 20, what is taught and shown by lvri et al is a method comprising: metering a first fluid using an acoustic volume transducer (Col. 5,

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lines 13-34; microphone detects audible signal which is proportional to inspiratory flow rate..."both the flow rate and the tidal volume can then be used to determine when the ejector should eject droplets and at what mass flow rate ..."); converting the first fluid to an aerosol (Col. 5, lines 12-14 and Col. 6, lines 40-54)); and outputting the aerosol (Col. 5, lines 28-31 and Col. 6, lines 47-54). It is therefore inherent that the device of lvri et al has a medium storing instructions to cause its processor to carry out the method claimed above Col. 5, lines 13-34).

- 16. Claims 8, 16-17 and 22-27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5575310 to Kamen et al.
- 17. With regards to claim 8, what is taught and shown by Kamen et al is a processor configured to calculate an aerosol volume and to output a volume signal associated with the calculated aerosol volume; receive an acoustic signal representing an acoustic property of a volume; calculate, using the received acoustic signal, a quantity associated with a first volume; receive the volume signal and output a signal for controlling a valve, the output signal being associated with the received acoustic signal and with the received volume signal (The examiner has interpreted that the volume of aerosol and fluid are the same entity, and also it is inherent that the fluid taught by Kamen et al could be an aerosol; Col. 2, line 20 to Col. 3, line 11; Col. 11, lines 50-57; Col. 12, lines 17-38). What is not taught or shown by Kamen et al is the use of a second processor, but in the disclosure of the instant application the applicant states that "for the purposes of the invention, processor 104 and the second processor can be the same processor."

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18. With regards to claim 16 and 17, what is taught and shown by Kamen et al is a method comprising: calculating a plurality of acoustic resonances associated with a variable volume chamber; calculating a volume of the variable-volume chamber, the calculated volume being associated with at least one of the plurality of acoustic resonances; receiving an aerosol volume signal associated with a volume of an aerosol; and outputting an amount of fluid, the amount of fluid being associated with the aerosol volume signal and with the calculated volume of the variable-volume chamber (The examiner has interpreted that the volume of aerosol and fluid are the same entity, and also it is inherent that the fluid taught by Kamen et al could be an aerosol; Col. 2, line 64 to Col. 3, line 11; Col. 11, lines 50-57; Col. 12, lines 17-38). It is therefore inherent that the device of Kamen et al has a medium storing instructions to cause its processor to carry out the method claimed above.

19. With regards to claims 22 and 25, what is taught and shown by Kamen et al is a method comprising: calculating a volume of the variable-volume chamber, the calculated volume being associated with an acoustic property of the variable-volume chamber; receiving an aerosol volume signal associated with a volume of an aerosol; and outputting an amount of fluid, the amount of fluid being associated with the aerosol volume signal and with the calculated volume of the variable-volume chamber (The examiner has interpreted that the volume of aerosol and fluid are the same entity, and also it is inherent that the fluid taught by Kamen et al could be an aerosol; Col. 2, line 64 to Col. 3, line 11; Col. 11, lines 50-57; Col. 12, lines 17-38). It is therefore inherent that

the device of Kamen et al has a medium storing instructions to cause its processor to carry out the method claimed above.

- 20. With regards to claims 23 and 26, what is taught and shown by Kamen et al is the method wherein the acoustic property of the variable-volume chamber is an acoustic resonance of the variable-volume chamber (Col. 7, line 60 to Col. 8, line 11).
- 21. With regards to claims 24 and 27, what is taught and shown by Kamen et al is the method wherein the acoustic property of the variable-volume chamber is an amplitude of an acoustic wave in the variable-volume chamber (Col. 9, lines 10-18; Col. 10, lines 39-44).

#### Allowable Subject Matter

22. Claims 2-4, 9-10, 15, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus S Lopez
Examiner
Art Unit 3743

Henra Bennett

atent Examiner

June 23, 2006

**ASL**